**SAMPLE CHILDREN ASSENT FORM**

***This document may serve as a guide or a template for your actual Child Assent Form. The information in this sample form MUST be included with the Parental Consent Form submitted to IRB for review. You may choose your own format if desired.***

In March of 1983 the Department of Health and Human Services issued further human subject regulations pertaining to children, entitled "Additional Protection for Children Involved as Subjects in Research" (45CFR46-Subpart D).

These regulations governing children in research situations decree that investigators need to take into consideration age, maturity, and psychological state of the participating children and include them in the consent form; and the investigator must solicit the assent of younger children. The regulation defines "assent" as the child's affirmative agreement to participate. "Mere failure to object should not, absent affirmative agreement, be construed as assent."

The following items should be addressed in an assent procedure (represented by an assent form, or by a prepared script of the explanation to be tendered), using language appropriate to the child's age and/or developmental level:

1. Why the child is asked to participate.

1. What is going to take place from the child's point of view.

1. The risk to the child.

1. The benefit to the child.

1. Identification of the researcher by name and telephone number in case questions should arise.

1. In non-therapeutic research, a statement that the child has a choice to participate or to withdraw at any time without negative consequences.

1. A statement that the child may retain a copy of the assent form.

1. Date and signature lines for the researcher and, if appropriate, for the child.